# UNITED STATES DISTRICT COURT
# FOR THE EASTERN DISTRICT OF PENNSYLVANIA

**FEDERAL TRADE COMMISSION**
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Plaintiff,

v.

**ENDO PHARMACEUTICALS INC.,**
1400 Atwater Drive
Malvern, Pennsylvania 19355;

**ENDO INTERNATIONAL PLC,**
1st Floor, Minerva House
Simmonscourt Road, Ballsbridge
Dublin 4, Ireland;

**TEIKOKU PHARMA USA, INC.,**
1718 Ringwood Avenue
San Jose, California 95131;

**TEIKOKU SEIYAKU CO., LTD.,**
567 Sanbonmatsu, Higashikagawa,
Kagawa 769-2695 Japan;

**WATSON LABORATORIES, INC.,**
400 Interpace Parkway
Parsippany, New Jersey 07054;

**ALLERGAN PLC,**
Clonshaugh Business and Technology Park,
Coolock
Dublin, D17 E400, Ireland; and

**IMPAX LABORATORIES, INC.,**
30831 Huntwood Avenue
Hayward, California 94544

Defendants.

Case Number:

COMPLAINT

**Complaint for Injunctive and Other Equitable Relief**

Plaintiff, the Federal Trade Commission ("FTC"), by its designated attorneys, petitions this Court, pursuant to Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), for a permanent injunction and other equitable relief against Defendants Endo Pharmaceuticals Inc.; Endo International plc; Teikoku Pharma USA, Inc.; Teikoku Seiyaku Co., Ltd.; Watson Laboratories, Inc.; Allergan plc; and Impax Laboratories, Inc.; to undo and prevent their unfair methods of competition in or affecting commerce in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), and an acquisition in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18.

## I. Nature of the Case

1. This case challenges anticompetitive reverse-payment agreements orchestrated by Endo to prevent lower-cost generic competition to its two most important branded prescription drug products. In 2009, Endo generated close to $1 billion from Opana ER, an opioid drug, and Lidoderm, a lidocaine patch, comprising approximately 64% of Endo's total annual revenues. The threat of generic entry for either of these products posed significant financial risks for Endo. Endo knew that generic competition would decimate its sales of the corresponding branded product and that any delay in generic competition would be highly profitable for Endo, but very costly for consumers. Faced with these threats to its lucrative drug franchises, Endo bought off its potential generic competitors.

2. In June 2010, Endo agreed to pay Impax to abandon its patent challenge and forgo entering the market with its lower-cost generic version of Opana ER for 2½ years, until January 2013. This payment included two separate components. First, Endo guaranteed that Impax would receive supracompetitive profits by being the only seller of generic Opana ER during its first 180 days on the market. Even though Endo had the legal right and financial incentive to compete with an authorized generic version of Opana ER as soon as Impax entered with its generic

product, Endo agreed that it would refrain from offering an authorized generic Opana ER product during Impax's initial 180 days of marketing (a "no-AG commitment"). If market conditions were to change to devalue this no-AG commitment, Endo further agreed to pay Impax a cash amount based on Impax's expected profits for that six-month period of generic exclusivity. Second, Endo agreed to pay Impax up to $40 million purportedly for an independent development and co-promotion deal. The financial terms of this deal, however, made no business or economic sense for Endo independent of Impax's agreement to stay off the market for over 2½ years. To date, Endo has paid Impax over $112 million from these two components.

3. In May 2012, Endo and its partner Teikoku agreed to pay Watson (now Allergan) to abandon its patent challenge and forgo entry with its lower-cost generic version of Lidoderm for more than a year until September 2013. This payment also included two components. First, Endo agreed to refrain from marketing an authorized generic version of Lidoderm during the first 7½ months of Watson's generic sales. Second, Endo agreed to provide Watson with branded Lidoderm patches valued at $96 to $240 million "at no cost," which Watson could then sell through its distribution subsidiary for pure profit. In total, Endo's payment to Watson was worth at least $250 million.

4. The purpose and effect of these anticompetitive agreements was to ensure that Endo would not face generic competition for Opana ER until January 2013 and for Lidoderm until September 2013. As a result, patients were denied the opportunity to purchase lower-cost generic versions of Opana ER and Lidoderm, forcing them and other purchasers to pay hundreds of millions of dollars a year more for these medications.

## II. Jurisdiction and Venue

5. This Court has subject matter jurisdiction over this action pursuant to 15 U.S.C. §§ 45(a) and 53(b), and 28 U.S.C. §§ 1331, 1337(a), and 1345.

6. This Court has personal jurisdiction over each Defendant pursuant to 15 U.S.C. § 53(b) and because each Defendant has the requisite constitutional contacts with the United States of America.

7. Venue in this district is proper under 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) and (c), and under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b). Each Defendant resides, transacts business, committed an illegal or tortious act, or is found in this District.

8. Defendants' general business practices and the unfair methods of competition alleged herein are "in or affecting commerce" within the meaning of Section 5 of the FTC Act, 15 U.S.C. § 45, and as defined in Section 1 of the Clayton Act, 15 U.S.C. § 12.

9. Defendant Watson's acquisition of an exclusive field-of-use license constitutes an acquisition subject to Section 7 of the Clayton Act, 15 U.S.C. § 18.

10. Each Defendant is, and at all times relevant herein has been, a corporation, as "corporation" is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

## III. The Parties

11. Plaintiff Federal Trade Commission ("FTC") is an independent administrative agency of the United States Government, established, organized, and existing pursuant to the FTC Act, 15 U.S.C. § 41 *et seq.*, with its principal offices in Washington, D.C. The FTC is vested with authority and responsibility for enforcing, *inter alia*, Section 5 of the FTC Act, 15 U.S.C. § 45, and is authorized under Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), to initiate court proceedings to enjoin violations of any law the FTC enforces and to seek equitable monetary remedies.

12. Defendant Endo Pharmaceuticals Inc. is a for-profit Delaware corporation, with its principal place of business at 1400 Atwater Drive, Malvern, Pennsylvania 19355. Endo Pharmaceuticals is engaged in the business of, among other things, developing, manufacturing,

and marketing branded drug products. In 2014, Endo Pharmaceuticals' revenues totaled $969 million. Endo Pharmaceuticals entered into the anticompetitive agreements challenged in this complaint.

13. Defendant Endo International plc is the parent company of Endo Pharmaceuticals Inc. Endo International is a for-profit Ireland corporation, with its global headquarters at 1st Floor, Minerva House, Simmonscourt Road, Ballsbridge, Dublin 4, Ireland, and its U.S. headquarters in Malvern, Pennsylvania. Endo International had $2.9 billion in revenues in 2014. At the time of the anticompetitive Opana ER agreement challenged in this complaint, Endo Pharmaceuticals Holdings Inc. was the parent of Endo Pharmaceuticals Inc. By the time of the anticompetitive Lidoderm agreement challenged in this complaint, Endo Pharmaceuticals Holdings Inc. was doing business as Endo Health Solutions Inc. The corporate officers of the parent entity negotiated and approved the Opana ER and Lidoderm agreements and the president signed them. Through a series of name changes, acquisitions, and corporate restructurings, Endo Health Solutions Inc. is now doing business as Endo International plc.

14. Defendant Teikoku Pharma USA, Inc. is a for-profit California corporation, having its principal place of business at 1718 Ringwood Avenue, San Jose, California 95131. Teikoku Pharma, through its parent company Teikoku Seiyaku Co. Ltd., is one of the largest pharmaceutical patch manufacturers in the world. Teikoku Pharma entered into the anticompetitive agreement concerning Lidoderm challenged in this complaint.

15. Defendant Teikoku Seiyaku Co., Ltd. is the for-profit parent company of Teikoku Pharma with its headquarters at 567 Sanbonmatsu, Higashikagawa, Kagawa 769-2695 Japan. Teikoku Seiyaku entered into the anticompetitive agreement concerning Lidoderm challenged in this complaint.

16. Defendant Watson Laboratories, Inc. is a for-profit Nevada corporation, having its

principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Watson is engaged in developing, manufacturing, marketing, and distributing generic pharmaceutical products, among other things. Watson Laboratories entered into the anticompetitive agreement concerning Lidoderm challenged in this complaint.

17. Defendant Allergan plc is the parent company of Watson Laboratories. Allergan is a for-profit Ireland corporation, with its corporate headquarters at Clonshaugh Business and Technology Park, Coolock, Dublin, D17 E400, Ireland, and its operational headquarters in Parsippany, New Jersey. At the time of the anticompetitive Lidoderm agreement challenged in this complaint, Watson Laboratories was a wholly-owned subsidiary of Watson Pharmaceuticals, Inc. The corporate officers of Watson Pharmaceuticals, Inc. negotiated the Lidoderm agreement and its chief legal officer signed it. Through a series of name changes, acquisitions, and corporate restructuring, Watson Pharmaceuticals is now doing business as Allergan plc.

18. Defendant Impax Laboratories, Inc. is a for-profit Delaware corporation, with its principal place of business at 30831 Huntwood Avenue, Hayward, California 94544. Impax engages in the business of, among other things, developing, manufacturing, and marketing generic drugs. In 2014, Impax had $596 million in net revenue. Impax entered into the anticompetitive agreement concerning Opana ER challenged in this complaint.

## IV. Background

### A. Federal law facilitates approval of generic drugs

19. The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 21 U.S.C. §§ 355(b)(2) and 355(j) and 35 U.S.C. § 271(e), establishes procedures designed to facilitate competition from lower-priced generic drugs, while maintaining incentives for

pharmaceutical companies to invest in developing new drugs.

20. A company seeking to market a new pharmaceutical product must file a New Drug Application ("NDA") with the U.S. Food and Drug Administration ("FDA") demonstrating the safety and efficacy of the new product. These NDA-based products generally are referred to as "brand-name drugs" or "branded drugs."

21. The FDA requires brand-name drug manufacturers to identify any patents that the manufacturer believes reasonably could be asserted against a generic manufacturer that makes, uses, or sells a generic version of the branded drug. The manufacturer must submit these patents for listing in an FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the Orange Book) within 30 days of issuance of the patent. 21 C.F.R. § 314.53.

22. A company seeking to market a generic version of a branded drug may file an Abbreviated New Drug Application ("ANDA") with the FDA. The generic applicant must demonstrate that its generic drug is therapeutically equivalent to the brand-name drug that it references and for which it seeks to be a generic substitute. Upon showing that the generic drug is therapeutically equivalent to the already-approved branded drug, the generic manufacturer may rely on the studies submitted in connection with the already-approved branded drug's NDA to establish that the generic drug is safe and effective. 21 U.S.C. § 355(j)(2)(A)(iv).

23. The FDA assigns a generic drug an "AB" rating if it is therapeutically equivalent to a brand-name drug. An AB-rated generic drug is the same as a brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. A generic drug also must contain identical amounts of the same active ingredient(s) as the brand-name drug, although its inactive ingredients may vary.

24. When a brand-name drug is covered by one or more patents listed in the Orange

Book, a company seeking to market a generic version of that drug before the patents expire must make a "paragraph IV certification" in its ANDA certifying that the patents are invalid, unenforceable, and/or will not be infringed by the generic drug.

25. If a company makes a paragraph IV certification, it must notify the patent holder of its certification. If the patent holder initiates a patent infringement suit against the company within 45 days of receiving such notice, the FDA may not grant final approval of the ANDA until the earliest of: (1) patent expiry; (2) district court resolution of the patent litigation in favor of the generic company; or (3) the expiration of an automatic 30-month stay.

26. When a generic drug otherwise meets the FDA's criteria for approval but final approval is blocked by statute or regulation, such as the Hatch-Waxman 30-month stay, the FDA will tentatively approve the relevant ANDA. Tentative approval does not permit an ANDA filer to market its generic version of the drug. The FDA can issue final approval of a tentatively-approved drug once the relevant 30-month stay expires.

27. The Hatch-Waxman Act provides the first generic company or companies filing an ANDA containing a paragraph IV certification ("first filer") with a period of protection from competition with other ANDA filers. This is referred to as the "180-day exclusivity" or "first-filer exclusivity" period. The Supreme Court observed that the 180-day exclusivity period "can prove valuable, possibly worth several hundred million dollars" to the first filer.

28. A branded drug manufacturer can market a generic version of its own brand product at any time, including during the first filer's exclusivity period. In that case, no ANDA is necessary because the manufacturer already has approval to sell the drug under its NDA. Such generics commonly are known as "authorized generics." An authorized generic is chemically identical to the brand drug, but is sold as a generic product, typically through either the brand manufacturer's subsidiary or through a third party.

29. In the absence of generic competition, a branded drug manufacturer typically will not undercut the profits on its branded drug by introducing a lower-priced authorized generic version of that drug. When an ANDA filer enters, however, an authorized generic may become attractive to the NDA holder as a means of maintaining some of the revenue it otherwise would lose to the generic competitor.

30. If an NDA holder discontinues the relevant drug, then the FDA moves the drug covered by the NDA to the Orange Book's Discontinued Drug Product List. Generic drugs referencing the discontinued NDA still may be sold, but they will not be listed in the Orange Book as AB-rated to any branded product.

**B. State law encourages substitution of AB-rated generic drugs for brand drugs**

31. All 50 states and the District of Columbia have drug substitution laws that encourage and facilitate substitution of lower-cost AB-rated generic drugs for branded drugs. When a pharmacist fills a prescription written for a branded drug, these laws allow or require the pharmacist to dispense an AB-rated generic version of the drug instead of the more expensive branded drug, unless a physician directs or the patient requests otherwise. Conversely, these laws generally do not permit a pharmacist to substitute a non-AB-rated generic for a branded drug unless the physician specifically prescribes it by writing the chemical name of the drug, rather than the brand name, on the prescription.

32. State substitution laws were enacted in part because the pharmaceutical market does not function well. In a well-functioning market, a consumer selects and pays for a product after evaluating the product's price and quality. In the prescription drug market, however, a patient can obtain a prescription drug only if the doctor writes a prescription for that particular drug. The doctor who selects the drug, however, does not pay for it and generally has little incentive to consider price when deciding which drug to prescribe. Instead, the patient, or in

most cases a third-party payer such as a public or private health insurer, pays for the drug. But these purchasers have little input over what drug is actually prescribed.

33. State substitution laws are designed to correct this market imperfection by shifting the drug selection choice from physicians to pharmacists and patients who have greater financial incentives to make price comparisons.

### C. Competition from lower-priced generic drugs saves American consumers billions of dollars a year

34. The Hatch-Waxman Act and state substitution laws have succeeded in facilitating generic competition and generating large savings for patients, health care plans, and federal and state governments. The first generic competitor's product is typically offered at a 20% to 30% discount to the branded product. Subsequent generic entry creates greater price competition with discounts reaching 85% or more off the brand price. According to a 2010 Congressional Budget Office report, the retail price of a generic is 75% lower, on average, than the retail price of a brand-name drug. In 2014 alone, the Generic Pharmaceutical Association reported that use of generic versions of brand-name drugs saved the U.S. healthcare system $254 billion.

35. Because of these price advantages and cost savings, many third-party payers of prescription drugs (e.g., health insurance plans and Medicaid programs) have adopted policies to encourage the substitution of AB-rated generic drugs for their branded counterparts. As a result of these policies and lower prices, many consumers routinely switch from a branded drug to an AB-rated generic drug upon its introduction. Consequently, AB-rated generic drugs typically capture over 80% of a branded drug's unit and dollar sales within six months of market entry.

36. Consumers also benefit from competition between an authorized generic drug and an ANDA-based generic drug. Empirical evidence shows that competition from an authorized generic drug during the first-filer's 180-day exclusivity results, on average, in retail prices that

are 4% to 8% lower and wholesale prices that are 7% to 14% lower than prices without authorized generic competition.

37. Competition from an authorized generic also typically has a significant financial impact on the first ANDA entrant. An authorized generic typically takes a significant share of the first ANDA entrant's generic sales, thereby reducing revenues during its 180-day exclusivity period by an average of 40% to 52%. Thus, if a brand manufacturer agrees to refrain from launching an authorized generic, it can double the first-filer's revenues during the 180-day exclusivity period. This financial impact is well-known in the pharmaceutical industry.

## V. Anticompetitive Conduct Concerning Opana ER

### A. Opana ER was a successful and rapidly growing branded drug

38. Oxymorphone is a semi-synthetic opioid, originally developed over one hundred years ago. Opioids are one of the world's oldest known classes of drugs, and they have long been used to relieve pain. The FDA first approved oxymorphone in 1960.

39. Opana ER is an extended-release formulation of oxymorphone. The FDA approved Opana ER (NDA No. 021610) in June 2006 "for the relief of moderate to severe pain in patients requiring continuous, around-the-clock opioid treatment for an extended period of time." Unlike immediate-release drugs, extended-release medications like Opana ER have special coatings or ingredients that control how fast the active ingredient is released from the pill into the patient's body. Compared to an immediate-release oxymorphone formulation, Opana ER provides longer-lasting, 12-hour pain relief that allows the patient to take fewer pills each day.

40. Endo launched Opana ER in 2006 as the only extended-release version of oxymorphone on the market. The drug, available in seven dosage strengths (5, 7.5, 10, 15, 20, 30, and 40 mg), is used to treat pain for a wide variety of conditions, ranging from chronic back problems to cancer.

41. Opana ER quickly became Endo's second best-selling drug. After a modest start of $5 million in sales in 2006, sales grew to $172 million in 2009. First quarter 2010 sales of $66 million indicated continued growth.

42. Endo sells Opana ER at prices far above Endo's cost of manufacturing the product, making Opana ER highly profitable. Even accounting for other direct expenses Endo allocates to selling and marketing Opana ER, Endo's profit margin on Opana ER, ranging between [redacted] and [redacted], is substantial.

**B. Potential generic competition threatened Endo's growing Opana ER business**

43. Opana ER's increasing sales drew the attention of numerous generic companies. Opana ER was an attractive target for generic drug makers because oxymorphone had been available for decades and was not subject to any meaningful patent protection. When Endo launched Opana ER in 2006, it only listed a single patent, No. 5,128,143 (the "'143 patent), in the Orange Book covering Opana ER. The '143 patent was not a meaningful, long-term barrier to generic competition because it was set to expire in September 2008. Endo's New Dosage Form exclusivity was set to expire in June 2009. With growing sales and no meaningful patent protection identified in the Orange Book, numerous generic entrants began preparing ANDAs for generic versions of Opana ER.

44. Following notice that a generic company had filed an ANDA to market a generic version of Opana ER, Endo listed three additional patents in the Orange Book in October 2007, well over a year after launching Opana ER.

45. On October 2, 2007, Endo listed Patent No. 7,276,250 (the "'250 patent") relating to a mechanism for controlling the release of a drug's active ingredient over an extended period of time. This patent expires in 2023.

46. On October 19, 2007, Endo listed two additional patents pertaining to a controlled

release mechanism—No. 5,662,933 (the "'933 patent") and No. 5,958,456 (the "'456 patent"). These patents had been issued by the U.S. Patent and Trademark Office up to a decade earlier—in 1997 and 1999, respectively. Endo failed to list the '456 and '933 patents in the Orange Book within 30 days of the FDA approving Endo's NDA for Opana ER as required under 21 C.F.R. § 314.53. The '933 and '456 patents expired in August 2013.

47. Eventually, at least nine companies submitted ANDAs seeking approval to market a generic version of Opana ER, including Impax, Actavis, and Watson. Each company included a paragraph IV certification asserting that its proposed generic product did not infringe Endo's patents and/or that Endo's patents were invalid or unenforceable. In response to each paragraph IV certification, Endo filed a patent infringement case, asserting that the generic product infringed either the '456 patent, the '933 patent, or both. Endo never asserted that any of the generic products infringed the '250 patent.

48. Impax submitted its ANDA, No. 79-087, on June 29, 2007 seeking approval to market a generic version of Opana ER. Although the FDA initially accepted the ANDA for substantive review, it later rescinded that acceptance due to certain deficiencies. Impax re-submitted ANDA No. 79-087, and the FDA accepted the application as of November 23, 2007.

49. On December 13, 2007, Impax notified Endo that it had submitted ANDA No. 79-087 with a paragraph IV certification stating that Impax's proposed generic product did not infringe Endo's '933 or '456 patents.

50. On January 25, 2008, Endo sued Impax for allegedly infringing the '456 and '933 patents. Because Endo sued Impax within 45 days of its paragraph IV notification, an automatic 30-month stay was imposed. This stay prevented the FDA from granting final approval to Impax's ANDA until June 14, 2010, absent an earlier court finding that Impax's product did not infringe Endo's patents or that the patents were invalid or unenforceable.

51. Impax was the first generic company to file an ANDA with a paragraph IV certification for the 5, 10, 20, 30, and 40 mg strengths of Opana ER. Impax received first-filer exclusivity for those dosage strengths, precluding the FDA from approving any other generic versions of Opana ER until 180 days after Impax's generic launch. These dosage strengths account for over 95% of all Opana ER sales. Given Impax's first-filer status, if Endo could delay Impax's entry, Endo would delay all generics from entering the market for the 5, 10, 20, 30, and 40 mg dosages of Opana ER.

### C. Endo paid Impax to drop its patent challenge and refrain from competing until January 2013

52. Throughout the first half of 2010, Impax prepared to launch its generic version of Opana ER at the expiration of the Hatch-Waxman 30-month stay on June 14, 2010, even if the patent challenge remained unresolved. Such generic entry is commonly referred to as an "at-risk launch."

53. On May 13, 2010, the FDA tentatively approved Impax's application for a generic version of Opana ER; final approval had to wait one month for the expiration of the Hatch-Waxman stay. Following the FDA's grant of tentative approval, the prospect of an Impax at-risk launch gained momentum. On May 13, 2010, Impax CEO Larry Hsu instructed his top executives to "alert" the Board of Directors of a "potential oxymorphine [*sic*] launch" and that "we will have a special Board conference call when we do decide to launch at risk on a later date." In materials presented to the Board of Directors that same month, Impax changed the "Current Assumption[]" for Opana ER from "no launch" to "At Risk Launch."

54. As of May 20, 2010, Impax had completed process validation, demonstrating that its manufacturing process was capable of consistently producing commercial quantities of generic Opana ER. Process validation is one of the final steps required by the FDA before

launch. In addition, Impax had produced nine of the 17 lots required for launch quantities (equivalent to three months of generic market supply) and had sufficient inventory of active pharmaceutical ingredient to complete the remaining lots. Impax had also requested authorization from the Drug Enforcement Agency to purchase the additional active pharmaceutical ingredient needed to produce larger quantities of generic oxymorphone ER.

55. Impax's impending launch presented a substantial risk to Endo's Opana ER monopoly. Endo knew that entry of AB-rated generic versions of Opana ER would cause Endo's Opana ER sales to drop rapidly and dramatically—possibly as much as 85% within a year.

56. To protect and extend its Opana ER franchise in the face of potential generic entry, Endo had been working on a reformulated "crush resistant" version of Opana ER ("Reformulated Opana ER") that would not be subject to automatic substitution from generic versions of its original formulation of Opana ER ("Original Opana ER"). Endo did not publicly disclose its reformulation plans.

57. Endo knew that the success of Reformulated Opana ER would hinge on whether Endo could introduce the product before it faced AB-rated generic competition for Original Opana ER. It is well known in the pharmaceutical industry that if generic versions of the original product (here, Original Opana ER) enter the market before the brand's follow-on product (here, Reformulated Opana ER), the follow-on product is likely to be much less successful. Indeed, Endo predicted that if a generic version of Original Opana ER were already on the market when it introduced Reformulated Opana ER, the reformulated version would capture only 30% to 32% of the Original Opana ER volumes.

58. In contrast, if Endo were to launch Reformulated Opana ER before generic entry, then Endo could expect to convert virtually the entire franchise to its reformulated product.

Given these market realities, industry analysts have observed that "it is essential that the brand holder switch their patents to the new formulation before generic launch."

59. Endo knew, however, that it would be unable to obtain FDA approval for its Reformulated Opana ER and convert the market before Impax could enter with its generic version of Original Opana ER. Endo, therefore, decided to purchase the time it needed by paying Impax not to compete until January 2013.

60. On or about June 8, 2010—just a week before Impax was expected to receive final FDA approval for its generic Opana ER and after two days of the patent infringement trial—Endo and Impax reached a settlement embodied in two documents: (1) a Settlement and License Agreement; and (2) a Development and Joint Promotion Agreement (hereinafter, together the "Opana ER Agreement").

61. Under the Opana ER Agreement, Endo agreed to pay Impax to abandon its patent challenge and to refrain from launching its generic version of Opana ER until January 1, 2013, approximately eight months before the expiration of the patents asserted in the infringement suit. This payment included two separate components. First, Endo guaranteed that Impax would receive a cash value commensurate with the supracompetitive profits that come with being the only seller of generic Opana ER for 180 days ("Guaranteed No-AG Payment"). Second, Endo agreed to pay Impax up to $40 million purportedly for an independent development and co-promotion deal ("Side Deal Payment").

62. Impax could not have obtained the Guaranteed No-AG Payment and the Side Deal Payment even had it won the patent infringement litigation with Endo.

**Guaranteed No-AG Payment**

63. Endo had the legal right and financial incentive to compete with an authorized generic version of Opana ER as soon as Impax entered with its generic product. Under the Opana

ER Agreement, however, Endo agreed not to offer a competing authorized generic Opana ER product during Impax's 180-day exclusivity period for the 5, 10, 20, 30, and 40 mg strengths.

64. The no-AG commitment was extremely valuable to Impax. With a no-AG commitment, the first filer's revenue will approximately double on average compared to what the first filer would make if it faced authorized generic competition. A first filer makes significantly more without generic competition because: (1) the authorized generic takes a significant share of generic sales from the first filer; and (2) competition between the first-filer generic and the authorized generic drives down generic drug prices. The financial effects of an authorized generic on the first-filer generic are well-known in the pharmaceutical industry.

65. The no-AG commitment was costly to Endo. Brand companies often introduce AGs to stem the large losses that result from the rapid shift from sales of branded drugs to cheaper generic products. Before settlement, Endo had been planning to launch an authorized generic if Impax launched at risk, estimating $25 million in authorized generic revenues during the first six months following generic entry. Endo forecasted that launching an authorized generic would recoup as much as 35% of the brand Opana ER revenues it expected to lose during that time.

66. Impax suspected, however, that Endo was planning to shift the market to a reformulated version of Opana ER before the negotiated entry date and recognized that such a move would both undermine the value of the no-AG commitment as well as decimate the potential sales for Impax's first-to-file generic product. Endo denied any plans to introduce a reformulated version of Opana ER, despite its active ongoing efforts to do so.

67. Notwithstanding Endo's assurances, Impax sought to "protect [itself] from making no money." Impax proposed ways to address its concern through provisions that would

expedite generic entry if Endo successfully introduced a reformulated product. Endo, however, rejected these proposals in favor of a so-called "Endo Credit."

68. Under the Endo Credit arrangement, Endo agreed to a "make good payment" to ensure that Impax would receive the supracompetitive profits that come with being the only seller of generic Opana ER even if Endo devalued the no-AG commitment by shifting the market to Reformulated Opana ER. Specifically, if, by the fourth quarter of 2012, Original Opana ER sales fell by more than 50% from the peak quarterly sales between the third quarter of 2010 and the third quarter of 2012, Endo would provide Impax with a cash payment. The dollar value of the Endo Credit was based on a formula designed to approximate Impax's expected profits as the only seller of a generic version of Opana ER assuming Endo had not launched Reformulated Opana ER. As Endo itself has explained, the Endo Credit was to ensure that Impax received "the expected bargained for benefit" of the no-AG commitment.

69. Ultimately, when Endo introduced Reformulated Opana ER and discontinued Original Opana ER before Impax's generic Opana ER entry date under the settlement, the value of the no-AG commitment fell and triggered Endo's obligation to pay Impax the Endo Credit, resulting in a payment from Endo to Impax of more than $102 million.

**Side Deal Payment**

70. On or about the same day that Endo and Impax entered into the Settlement and License Agreement, Endo and Impax also entered into a development and co-promotion deal concerning a potential treatment for Parkinson's disease, code-named IPX-203. At the time of the deal, IPX-203 was still in the very early stages of pre-clinical development: Impax had not yet developed a formulation for the product, submitted an Investigational New Drug application to the FDA, or initiated any sort of clinical trials. Fewer than 1% of drugs in pre-clinical development ultimately receive FDA approval.

71. The development and co-promotion deal provided Impax with immediate cash, plus the potential for more in the future. Under the deal, Endo agreed to pay Impax $10 million in cash up front and up to $30 million in additional milestone payments. If Impax succeeded in developing the drug and obtaining FDA approval, Endo would have the right to co-promote the product in the United States to non-neurologists and to receive [redacted] to 100% of the profits generated by prescriptions from those doctors.

72. The FDA granted final approval to Impax's ANDA for generic Opana ER for the 5, 10, 20, and 40 mg dosages on June 14, 2010 and for the 30 mg dosage on July 22, 2010. Absent the Opana ER Agreement, Impax would have been legally permitted to launch its generic product at risk.

**D. Endo's payment to Impax is large**

73. At the time of the settlement, Impax expected to, and did, derive significant value from the Opana ER Agreement in the form of: (1) a Side Deal Payment of at least $10 million and up to $40 million; and (2) a Guaranteed No-AG Payment of at least $37 million and potentially more than $100 million. To date, Endo has paid Impax more than $112 million under the Opana ER Agreement.

74. Endo's payment to Impax, both expected and actual, is large. First, the $10 million payment under the development and co-promotion deal was guaranteed and non-refundable.

75. Second, the structure of the Guaranteed No-AG Payment ensured that Impax would derive significant financial value from either the no-AG commitment or the Endo Credit or both. Indeed, as Impax's chief negotiator explained, the possibility that Impax would receive little value from either the no-AG commitment or the Endo Credit was "so unlikely it wasn't worth worrying about."

76. Before the settlement, Impax expected that Endo would launch an authorized generic to compete with Impax's generic Opana ER product. According to Impax's internal forecasts, competition from an authorized generic would take 40% to 50% of Impax's expected unit sales and decrease the price of the remaining sales by more than 36%. With the no-AG commitment, Impax would not face this competition, retaining all generic Opana ER sales for six months at a supracompetitive price. At the time of the Opana ER Agreement, the value of the no-AG commitment to Impax ranged from $37 to $77 million.

77. If, however, consistent with its strategic plan, Endo destroyed the market opportunity for Impax's generic version of Original Opana ER, including the value of the no-AG commitment, then Impax would receive a cash payment under the Endo Credit. The Endo Credit payment was based on various factors affecting Impax's expected profits during the no-AG commitment period, including the generic substitution rate, expected generic pricing as a percentage of brand pricing, and Impax's net profit margin. If triggered, Endo's likely payment under the Endo Credit would be at least $46 million and could exceed $100 million (as actually occurred).

78. Thus, as of the time the parties entered into the Opana ER Agreement, the total value of Endo's expected payment, including the Guaranteed No-AG Payment (at least $37 million) and the Side Deal Payment (at least $10 million), was at least $47 million and potentially greater than $100 million.

79. Endo's actual and likely payment to Impax far exceeds any reasonable measure of avoided litigation costs in the parties' underlying patent litigation. The settlement occurred late in the litigation, after trial had begun. By that time, Endo already had expended more than $7 million in litigation fees and costs. Any remaining litigation costs would have been a small

fraction of Endo's payment, whether measured against the actual amount paid ($112 million) or any amount anticipated at the time of the Opana ER Agreement.

80. Endo's payment was designed to, and did, induce Impax to abandon its Opana ER patent challenge and agree to refrain from marketing its generic Opana ER product until January 2013. Impax's decision to settle was driven not by the strength of Endo's patent protection for Opana ER, but by the large payment Endo made to Impax. As Impax's president of generics stated to the CEO: "That money is really important as we all know."

81. Endo's payment exceeded the amount Impax projected to earn by launching its generic version of Opana ER. In May 2010—just a month before entering into the settlement—Impax projected its generic Opana ER product would generate about $48 million in profits in its first 2½ years on the market—less than half the amount Endo already has paid Impax under the Opana ER Agreement. In fact, Endo's payment exceeded the sales generated by Impax's five new generic launches in 2013, including its generic version of Original Opana ER. As Impax explained in an SEC filing, its net income growth in 2013 was "primarily attributable" to Endo's $102 million cash payment under the Opana ER Agreement.

82. Endo was willing to make this large payment to Impax because the January 2013 entry date would enable Endo to maintain monopoly prices for Opana ER throughout that period and beyond.

**E. Endo's large payment to Impax is not justified**

83. Endo's large payment to Impax cannot be justified solely as compensation for the services to be performed by Impax.

84. The Guaranteed No-AG Payment is not compensation for goods or services provided by Impax to Endo. Indeed, Impax was not required to provide any goods or perform any service in exchange for the more than $102 million Guaranteed No-AG Payment.

85. The purpose and effect of Endo's Guaranteed No-AG Payment was to induce Impax to abandon its patent challenge and agree not to compete with a generic version of Original Opana ER until January 2013. The payment is explicitly part of the Settlement and License Agreement and makes no economic sense absent Impax's agreement not to market a generic version of Opana ER until January 2013. Endo would not have agreed to the Guaranteed No-AG Payment without also securing Impax's agreement not to market a generic version of Opana ER until January 2013. Likewise, Impax would not have agreed to a January 2013 entry without also securing Endo's commitment to the Guaranteed No-AG Payment.

86. In addition, Endo's Side Deal Payment cannot be justified solely as compensation for the services to be performed by Impax under the deal. Instead, the purpose and effect of Endo's payment was to induce Impax to abandon its patent challenge and agree not to compete with a generic version of Original Opana ER until January 2013. Endo would not have agreed to make the large Side Deal Payment without also securing Impax's agreement not to market a generic version of Opana ER until January 2013. Likewise, Impax would not have agreed to a January 2013 entry without also securing the large Side Deal Payment.

87. Substantial evidence shows the direct link between Endo's Side Deal Payment and Impax's agreement to the January 2013 entry date, including:

a. Endo and Impax never discussed a development agreement outside the context of settlement negotiations. Instead, the development deal and the Endo-Impax settlement agreement were negotiated and drafted at the same time, by the same people, and were held in escrow until both agreements were finalized.

b. Impax had tried unsuccessfully for years to find a partner willing to invest in the development of a neurological drug in return for the right to co-promote the drug only to non-neurologists. As Impax's CEO explained: [redacted]

[redacted]

c. Endo's substantial investment in the very early stages of drug development was contrary to the company's stated objective to invest in "marketed/market ready assets."

d. Despite the incompatibility with Endo's corporate development strategy, and the absence of any other interested investor, Endo was nonetheless willing to accept limited co-promotion rights for the early-stage development project.

e. The due diligence schedule for this purportedly independent business transaction was explicitly tied to the timing of the Opana ER patent trial and settlement negotiations. Due to the artificially compressed due diligence schedule and insufficient information on the proposed product, Endo based its financial valuation of the deal on a different Impax development project.

f. The $10 million up-front payment was [redacted]. And Endo has obtained little value in return for its large payment. Impax's development of the subject product, IPX-203, has been significantly delayed; over five years later, Impax still has not completed any of the development milestones, pushing back final FDA approval of the product until after 2020 (if ever).

88. In short, the financial terms of the development and co-promotion deal made no business or economic sense for Endo independent of Impax's agreement to defer generic Opana ER entry until January 2013. The development and co-promotion deal provided the vehicle for

Endo to pay Impax cash immediately as part of an overall compensation package to abandon its patent litigation and agree to stay out of the market for over 2½ years.

89. There are no other procompetitive benefits, countervailing efficiencies, or increases in consumer welfare from the Opana ER Agreement that outweigh the significant competitive harm caused by eliminating the risk of Impax's generic entry until January 2013.

90. Moreover, Endo's large payment to Impax was not reasonably necessary to achieve any potential procompetitive objective of the Opana ER Agreement.

**F. Endo settled with the other Opana ER first filer with no reverse payment, and a significantly earlier entry date**

91. On or about June 8, 2007, Actavis submitted ANDA No. 79-046 to the FDA for its generic version of Opana ER for the 5, 10, 20, and 40 mg dosages. After Endo listed the three patents purportedly relating to Opana ER in the Orange Book, Actavis submitted a paragraph IV certification stating that its proposed generic product did not infringe Endo's patents and/or that Endo's patents were invalid or unenforceable. On February 12, 2008, Actavis notified Endo that it had submitted ANDA No. 79-046 with a paragraph IV certification. On March 28, 2008, Endo sued Actavis for alleged infringement of only the '456 patent. Because Endo sued Actavis within 45 days of its paragraph IV notification, an automatic 30-month stay resulted.

92. On or about May 29, 2008, Actavis notified Endo that it had amended its ANDA for a generic version of Opana ER to include 7.5 and 15 mg dosages and submitted a paragraph IV certification stating that its proposed generic product did not infringe Endo's patents. On July 11, 2008, Endo sued Actavis for alleged infringement of only the '456 patent. Because Endo sued Actavis within 45 days of its paragraph IV notification, an automatic 30-month stay resulted, preventing the FDA from granting final approval to Actavis's ANDA until November

2010, absent an earlier court finding that Actavis's product did not infringe Endo's patents or that the patents were invalid or unenforceable.

93. Actavis was the first generic company to file an ANDA with a paragraph IV certification for the 7.5 and 15 mg dosage strengths of Opana ER. As the first filer, Actavis was eligible for 180 days of exclusivity for those two dosage strengths as against any other ANDA product.

94. In February 2009, less than one year into the patent litigation, Endo settled its suit against Actavis. Under the terms of the settlement, Endo granted Actavis a covenant not to sue and a license for the sole asserted patent, the '456 patent, to begin marketing its generic version of Opana ER on July 15, 2011. In addition, Endo granted Actavis a covenant not to sue for the '250 and '933 patents—the two other patents listed in the Orange Book that Endo had not asserted in the litigation. That settlement involved no payment from Endo to Actavis.

95. Although Actavis had a license to enter in 2011, it was blocked from launching any of the five dosage strengths for which Impax was eligible for 180-day exclusivity (5, 10, 20, 30, and 40 mg), until such exclusivity expired or was otherwise lost.

## VI. Anticompetitive Conduct Concerning Lidoderm

### A. Lidoderm is a highly successful, highly profitable brand-name drug

96. Lidocaine is a local anesthetic that prevents pain by blocking the signals at the nerve endings in the skin. The FDA first approved lidocaine for topical use in the early 1950s and has subsequently approved various topical lidocaine products for a number of different uses.

97. Lidoderm is a transdermal lidocaine patch indicated for relief of pain associated with post-herpetic neuralgia ("PHN"), a complication of shingles. In a minority of patients, shingles damages nerve fibers and skin, causing pain that can last for months or even years.

There is no known cure for PHN, but pharmaceutical products may offer temporary relief from PHN pain.

98. Lidoderm was developed by Teikoku. In May 1996, Teikoku submitted an NDA (No. 20-612) to the FDA seeking approval for Lidoderm. The FDA approved Lidoderm in March 1999.

99. Lidoderm is the only topical lidocaine patch indicated for the relief of pain associated with PHN and the only lidocaine formulation used as a first-line therapy for PHN pain. Unlike other first-line therapies for this condition (including antiepileptics and tricyclic antidepressants), Lidoderm is applied topically, resulting in minimal systemic absorption and a low risk of systemic side effects, drug-drug interactions, and drug-disease interactions. As a result, Lidoderm can be used as long as necessary, with minimal risk of the user developing a tolerance, dependence, or addiction. For these reasons, Lidoderm is a preferred therapy for treating PHN.

100. Under the terms of a November 1998 supply and manufacturing licensing agreement between Endo and Teikoku ("Lidoderm Supply and Manufacturing Agreement"), Endo has the exclusive right to sell Lidoderm in the United States. Endo purchases Lidoderm from Teikoku.

101. Endo launched Lidoderm in the United States in September 1999. U.S. sales of Lidoderm grew substantially over time, from $22.5 million in 2000 to $947.7 million in 2012. For much of this period, Lidoderm was Endo's best-selling product, accounting for up to 65% of the company's total net revenues.

102. As a unique treatment for relieving PHN pain, Lidoderm has been highly profitable for Endo. Before the entry of generic versions of Lidoderm, Endo sold branded Lidoderm at prices far above its costs of obtaining product from Teikoku and any royalties Endo

paid relating to the product without sacrificing unit sales or revenues. Even accounting for other direct expenses that Endo allocated to selling and marketing Lidoderm, Endo's profit margin on Lidoderm net sales was substantial, typically ranging between [redacted] and [redacted].

103. Endo regularly increased its list price, or wholesale acquisition cost ("WAC"), for Lidoderm without sacrificing unit sales. Between 2008 and 2013, Endo steadily increased its Lidoderm WAC from approximately $169 to more than $260 per box of 30 patches. Over that same time period, Endo's unit sales of Lidoderm in the United States remained fairly consistent, fluctuating between approximately 1.5 and 2.0 million boxes quarterly. Endo's ability to significantly increase WAC yet retain unit sales occurred despite the introduction of other products approved to relieve pain associated with PHN during the relevant time period.

**B. Potential generic competition threatened Endo's Lidoderm franchise**

104. Lidoderm's financial success drew the attention of several generic competitors. In November 2009, Watson filed ANDA No. 200-675 seeking approval to market a generic version of Lidoderm. Watson's application to the FDA contained a paragraph IV certification that Watson's generic product did not infringe U.S. patent No. 5,827,529 (the "'529 patent") and/or that the '529 patent was invalid or unenforceable. The '529 patent does not cover lidocaine, the active ingredient in Lidoderm, which has been used in medications for more than 50 years. Rather, it covers only certain lidocaine patch formulations containing specified ingredient quantities.

105. Teikoku owns the '529 patent. Under an amendment to the Lidoderm Supply and Manufacturing Agreement, Teikoku granted Endo an exclusive license under the patent to sell Lidoderm in the United States.

106. As to the remaining patents listed in the Orange Book for Lidoderm at the time of Watson's filing, Watson filed a paragraph III certification representing that it would not sell its generic product in the United States until those patents expired on May 2, 2012.

107. Watson was the first generic company to file an ANDA with a paragraph IV certification covering the '529 patent. Watson therefore became eligible for first-filer exclusivity, which could prevent the FDA from approving any other generic versions of Lidoderm until 180 days after Watson's generic launch. By delaying Watson's entry, Endo could delay all generic Lidoderm entry.

108. On or about January 14, 2010, Watson notified Teikoku of Watson's paragraph IV certification relating to the '529 patent. Under the amended supply and manufacturing agreement with Teikoku, Endo had the exclusive right to determine whether to sue Watson for infringement, the right to name Teikoku as a party if necessary for the action, and the right, with limited exceptions, to control litigation and settlement of any claims. On February 19, 2010, Endo and Teikoku sued Watson for infringement of the '529 patent in federal district court in Delaware.

109. Because Endo sued Watson within 45 days of its paragraph IV notification, an automatic 30-month stay was imposed. This stay prevented the FDA from granting final approval to Watson's ANDA until mid-July 2012, absent an earlier court finding that Watson's product did not infringe the '529 patent or that the '529 patent was invalid or unenforceable.

110. While the patent litigation was pending, Watson took significant steps to be ready to launch as soon as it received FDA approval for its generic Lidoderm product, including spending more than $40 million on its Salt Lake City manufacturing plant where it would manufacture the generic patches and purchasing millions of dollars of raw materials needed for

the patches. In addition, Watson projected revenues from generic lidocaine patch sales in its forecasts and budgets for the period beginning in late 2012 or early 2013.

111. Launching its generic Lidoderm product upon FDA approval would likely require an at-risk launch. In addressing that possibility for generic Lidoderm, Watson's CEO, Paul Bisaro, publicly stated that Watson has "never been shy" about launching at risk and that these launch preparations were not a "bluff," but a genuine commitment to launch its generic Lidoderm product upon FDA approval, even if the patent litigation had not yet concluded:

> Just for the record and this is an important point, to demonstrate our commitment to this product we've built onto our facility in Salt Lake. We spent $40 million and we're buying raw material today [February 2012], so we're spending millions of dollars preparing for this launch. So this is not a bluff; it's true.

112. Endo was closely monitoring the steps Watson was taking to prepare for a generic lidocaine patch launch and Watson's public statements about the likelihood of such a launch. Endo expected that competition from a generic product would lead to rapid and dramatic declines in the company's Lidoderm revenues. During the first year after generic entry, Endo predicted that its branded Lidoderm revenues would decrease by at least $500 million. Watson similarly forecasted a sharp decline in branded Lidoderm sales after a generic product entered the market.

113. In late June 2011, Watson prevailed with respect to claim construction of the '529 patent. As the Patent Case Management Judicial Guide notes: "The construction of patent claims plays a critical role in nearly every patent case. It is central to evaluation of infringement and validity, and can affect or determine the outcome of other significant issues such as unenforceability, enablement, and remedies."

114. Shortly after the adverse claim construction decision, Endo filed a separate federal court action against Watson alleging that Watson's generic product infringed three additional

patents that Endo had subsequently acquired—U.S. Patent Nos. 5,741,510 (the "'510 patent"), 6,096,333 (the "'333 patent"), and 6,096,334 (the "'334 patent"). Of these three patents, Endo listed only the '510 patent in the Orange Book. No 30-month stay resulted from this later patent litigation.

115. A six-day trial on the '529 patent infringement claims occurred in February 2012. Coming out of that trial, Watson was confident in its litigation position.

### C. Endo paid Watson to abandon its patent challenge and refrain from competing until September 2013

116. On May 28, 2012, Endo, Teikoku, and Watson settled both Lidoderm patent litigations ("the Lidoderm Agreement"), before a final decision was issued in either case. Although Endo had primary authority to negotiate a settlement, Teikoku's approval was necessary for the settlement to proceed.

117. Under the Lidoderm Agreement, Endo and Teikoku agreed to pay Watson to abandon its patent challenge and refrain from launching its generic version of Lidoderm for more than a year, until September 15, 2013. This payment included two separate components. First, Endo and Teikoku committed not to compete with an authorized generic for up to 7½ months ("No-AG Payment"). Second, Endo and Teikoku agreed to provide Watson's wholly-owned wholesale distributor with free branded Lidoderm product worth at least $96 million in 2013 and the possibility of additional free product worth up to approximately $240 million through 2015 ("Free Product Payment").

118. Watson could not have obtained the No-AG Payment or the Free Product Payment even if it had won the patent infringement litigation with Endo.

**No-AG Payment**

119. Endo had the legal right and financial incentive to compete with an authorized generic version of Lidoderm as soon as Watson entered with its generic product. Under the Lidoderm Agreement, however, Endo agreed not to compete with an authorized generic version of Lidoderm for 7½ months after September 15, 2013, unless a third party launched a generic Lidoderm product. In exchange, Watson agreed to pay Endo a 25% royalty on the gross profits from Watson's generic Lidoderm sales before entry of a second generic product. The parties characterized the No-AG Payment as a "partially exclusive" license.

120. The No-AG Payment was extremely valuable to Watson. Because of Watson's eligibility for first-filer exclusivity, the No-AG Payment ensured that Watson would not face generic lidocaine patch competition for at least 180 days—and up to 7½ months—after its launch.

121. The No-AG Payment was costly to Endo. Before settlement, Endo had been planning to launch an authorized generic if Watson launched at risk, estimating that it would earn $150 million in authorized generic net revenues during the first year following generic entry.

**Free Product Payment**

122. As part of the Lidoderm Agreement, Endo and Teikoku agreed to provide $12 million worth of branded Lidoderm product monthly from January through August 2013 to Watson through its wholly-owned distributor subsidiary. The product—worth a total of $96 million—was free to Watson: Watson paid Endo and Teikoku nothing for the branded product received under the Lidoderm Agreement. Endo and Teikoku further agreed to provide up to $144 million more in free branded Lidoderm in 2014 and 2015 if the FDA did not approve Watson's generic Lidoderm application. As stated in the Lidoderm Agreement, Endo provided this free branded product to Watson as "a good-faith, bargained-for-resolution of the claims at

issue in the Litigation." The cost to Endo and Teikoku of forgoing the profits that it otherwise would have made on the free branded product was roughly $90 million.

**D. Endo and Teikoku's payment to Watson is large**

123. The payment to Watson under the Lidoderm Agreement is large. The total value of Endo and Teikoku's expected payment to Watson, including the No-AG Payment and the Free Product Payment and discounting any royalties Watson paid to Endo, was at least $250 million.

124. Endo's commitment to refrain from selling an authorized generic for 7½ months and to forgo the profits from authorized generic sales that it would have made during that period resulted in hundreds of millions in gain for Watson at a substantial cost to Endo. Endo's commitment to refrain from selling an authorized generic would substantially increase Watson's expected generic Lidoderm revenues by allowing Watson to capture all generic Lidoderm sales, instead of splitting these sales with Endo's authorized generic. Additionally, as the only seller of generic Lidoderm, Watson could charge 33% more than if it faced competition from an authorized generic. In May 2012—the same month it entered into the Lidoderm Agreement—Watson prepared several forecasts projecting Watson's revenues and profits from generic Lidoderm sales. Based on these forecasts, Watson could expect to earn at least $214 million more in generic Lidoderm revenues during its first six months on the market if it did not face generic competition from an Endo authorized generic. Extending the effects of the no-AG commitment to the full 7½ months granted under the Lidoderm Agreement increases the value to at least $260 million.

125. The Free Product Payment was worth more than $90 million in additional compensation to Watson. Watson anticipated that it would sell the free branded product to customers at the prevailing market price, which was approximately 4% to 5% lower than the contemporaneous brand wholesale acquisition cost (commonly referred to as "WAC"). Thus, for

the $96 million of free branded product that Endo would supply to Watson in 2013, Watson could expect to profit by $91.2 to $92 million. Because Watson did not have any direct costs for the free branded product, its entire revenues were profit.

126. Any royalty Watson paid to Endo would not offset Endo and Teikoku's payment to Watson. Based on Watson's contemporaneous forecasts, its royalty payments to Endo would only amount to approximately $101 million, compared to Endo and Teikoku's payment in excess of $350 million.

127. Endo and Teikoku's payment far exceeds any reasonable measure of avoided litigation costs in the parties' underlying patent litigation. The settlement occurred late in the litigation, after a six-day trial and post-trial briefing. Collectively, Endo and Teikoku already had spent around $14 million on the litigation. Any remaining litigation costs would be a small fraction of Endo and Teikoku's total payment.

128. Endo and Teikoku's payment was designed to, and did, induce Watson to abandon its Lidoderm patent challenge and agree to refrain from marketing its generic Lidoderm product until September 2013. Watson's decision to settle was driven not by the strength of Endo's patent protection for Lidoderm, but by the large payment Endo and Teikoku made to Watson.

129. Indeed, Endo's payment exceeded the amount Watson projected to earn by launching its generic version of Lidoderm. Based on internal forecasts prepared around the time of settlement, Watson would earn at least $100 million more from the Lidoderm Agreement payment (even accounting for the royalty payments it would make to Endo) than it would earn by launching generic Lidoderm immediately following FDA approval in 2012.

130. Endo and Teikoku were nonetheless willing to make the large payment to Watson because the September 15, 2013 entry date would enable Endo to maintain monopoly prices for Lidoderm throughout that period.

**E. Endo and Teikoku's large payment is not justified**

131. Endo and Teikoku's payment to Watson cannot be justified solely as compensation for the services to be performed by Watson. In fact, Watson provided no services to Endo or Teikoku in exchange for the Lidoderm Agreement payment worth hundreds of millions of dollars.

132. Providing $96 million worth of free branded product to Watson through its wholesale distributor did not result in any significant procompetitive benefits. Watson's wholesale distributor sold the free branded product at prices comparable to what customers were paying other distributors.

133. The purpose and effect of Endo and Teikoku's large payment was to induce Watson to abandon its patent challenge and agree not to compete with a generic version of Lidoderm until September 15, 2013. Endo and Teikoku's commitment to forgo profitable Lidoderm authorized generic sales for 7½ months and provision of free branded product worth $96 million to Watson make no economic sense independent of securing Watson's agreement not to market a generic version of Lidoderm until September 15, 2013.

134. Likewise, Watson agreed not to compete with its own generic version of Lidoderm until September 2013 only because Endo and Teikoku shared its Lidoderm monopoly profits in the form of the No-AG Payment and the Free Product Payment. Without the large payment, Watson would not have agreed to refrain from competing until September 2013.

135. There are no other procompetitive benefits, countervailing efficiencies, or increases in consumer welfare from the Lidoderm Agreement that outweigh the significant competitive harm caused by eliminating the risk of Watson's generic entry until September 2013.

136. Moreover, Endo and Teikoku's payment to Watson was not reasonably necessary to achieve any potential procompetitive objective of the Lidoderm Agreement.

## VII. Monopoly Power

### A. Endo's monopoly power concerning Opana ER

137. Endo exercised monopoly power in a relevant market that is no broader than extended-release oxymorphone ("oxymorphone ER") tablets approved by the FDA for sale in the United States, through at least the end of 2013. There is substantial evidence of Endo's monopoly power. Endo and Impax had forecast a dramatic decline in the average price of oxymorphone ER following entry of an AB-rated generic version of Opana ER. For example, Impax estimated that within one year of generic entry, AB-rated generic versions of Opana ER would be priced at approximately 5% of the brand product's WAC and would capture up to 90% of unit sales.

138. Even without an AB rating, Endo expected generic entry to have a dramatic impact on Reformulated Opana ER's revenues and unit sales: "[I]f additional generic companies enter the market with generic non-crush resistant oxymorphone extended release tablets [original formulation], Endo will experience immediate, dramatic, and irreparable price erosion and loss of sales." Indeed, as Endo predicted, Impax's and Actavis's non-AB-rated generic oxymorphone ER products captured significant share from Reformulated Opana ER through competitive pricing, with discounts of up to 40% off the brand price. In 2013, Impax's and Actavis's generic versions of Opana ER accounted for approximately 28% of all oxymorphone ER unit sales for all dosage strengths in 2013, increasing to approximately 37% for the first half of 2014. These

results are consistent with Endo's own prediction that even non-AB-rated generics eventually would capture 40% or more of branded Opana ER sales.

139. If Endo were already facing robust competition to Opana ER, then the entry of generic oxymorphone ER would not have eroded the sales volume of branded Opana ER or the price of oxymorphone ER products so rapidly and dramatically.

140. In addition, other long-acting opioid products used to relieve moderate to severe pain have not meaningfully constrained Endo's pricing or sales of Opana ER. From 2007 to 2012, despite the availability of several other long-acting opioid products, Endo regularly increased the wholesale acquisition cost of Opana ER, from about $9 per pill (40 mg) to over $12 per pill (40 mg). During that same period, the entry of new branded long-acting opioid products, such as Embeda and Exalgo, had no discernable impact on Opana ER prices or unit sales.

141. Moreover, Opana ER is not reasonably interchangeable with other pain relief medications used to treat the same or similar conditions. As Endo itself represented to the FDA and the medical community, "there is no therapeutically equivalent or pharmaceutically alternative substitutable product" to Opana ER. The abrupt discontinuation of an opioid product can result in severe withdrawal symptoms. Switching a patient from one opioid to another presents serious underdosing and overdosing risks to the patient and requires careful medical monitoring. Therefore, patients that have begun a successful course of treatment with an opioid such as Opana ER are unlikely to switch to another pain medication for economic reasons.

142. From its launch in 2006 through 2012, Opana ER accounted for 90% to 100% of the unit sales of oxymorphone ER products. By the end of 2013, even with competition from Impax's and Actavis's generic oxymorphone ER products, Endo's branded Opana ER retained a 70% share of all oxymorphone ER unit sales because Endo converted the market to

Reformulated Opana ER prior to generic entry.

143. Substantial barriers to entry exist in the oxymorphone ER market. Potential new branded drug competitors need to conduct expensive clinical trials and obtain FDA approval. Potential sellers of generic oxymorphone ER also face substantial barriers to entry, including the need to obtain FDA approval, costly specialized equipment and facilities, and Endo's ability to trigger an automatic 30-month stay of FDA approval by filing a patent infringement lawsuit.

**B. Endo's monopoly power concerning Lidoderm**

144. Endo exercised monopoly power in the relevant market for lidocaine patches approved by the FDA for sale in the United States, through at least Watson's entry with a generic version of Lidoderm in September 2013. There is substantial evidence of Endo's monopoly power. Endo and Watson predicted a dramatic decline in the average price of lidocaine patches following generic entry. Additionally, Endo and Watson expected that competition from a generic product would lead to a rapid and dramatic decline in Endo's Lidoderm revenues. For example, Endo predicted that, during the first year after generic entry, its Lidoderm revenues would decrease by at least $500 million.

145. The data available since the entry of Watson's generic version of Lidoderm confirm the unique competitive impact of such entry on Lidoderm sales and prices. When Watson entered with its generic product, Endo reduced the price of branded Lidoderm as much as 40% in an effort to retain lidocaine patch sales. Nonetheless, within three months, Watson's generic product had captured over 70% of the lidocaine patch unit sales.

146. If Endo already were facing robust competition to Lidoderm, then the entry of generic competition to Lidoderm would not erode the sales volume of branded Lidoderm or the price of lidocaine patches so rapidly and dramatically.

147. In addition, other drugs used to treat PHN have not meaningfully constrained

Endo's pricing or sales of Lidoderm. Between 2008 and 2013, Endo steadily increased its Lidoderm WAC from approximately $169 to $260 per box of 30 patches. Over that same period, however, Endo's unit sales of Lidoderm in the United States remained largely stable, fluctuating between 1.5 and 2.0 million boxes quarterly. During that same period, the entry of new branded products approved to relieve pain associated with PHN, such as Qutenza, Horizant, and Gralise, had no discernible impact on Lidoderm prices or unit sales.

148. Moreover, because of its unique characteristics, Lidoderm is not reasonably interchangeable with other medications used to relieve pain associated with PHN. Unlike other PHN treatments, Lidoderm is a topical treatment that can be used at home and applied directly to the skin on the affected area. While other drug therapies, such as anticonvulsants and antidepressants, may be used in conjunction with lidocaine patches to improve results, they are not viewed by physicians as substitutes. As the head of Endo's Pain Management business explained: "Lidoderm was unique in the attributes that it presents to a physician and to a patient as they're seeking a therapy . . . [T]here really is not another product that is exactly like Lidoderm."

149. Before September 2013, Endo consistently held a 100% share of the relevant market for lidocaine patches.

150. Substantial barriers to entry exist in the lidocaine patch market. Potential new branded drug competitors need to conduct expensive clinical trials and obtain FDA approval. Potential sellers of generic lidocaine patches also face substantial barriers to entry, including the need to obtain FDA approval, costly specialized equipment and facilities to manufacture the patches, and Endo's ability to trigger an automatic 30-month stay of FDA approval by filing a patent infringement lawsuit.

### C. Watson's monopoly power concerning generic lidocaine patches

151. Watson exercised monopoly power in the relevant market of generic lidocaine patches approved by the FDA for sale in the United States, from September 2013 until Endo began selling an authorized generic in May 2014. While numerous other drugs are used to relieve pain associated with PHN (including branded Lidoderm), there is substantial evidence of Watson's monopoly power throughout the relevant time period. Both Endo and Watson predicted that generic lidocaine patch prices would fall considerably upon entry of the second generic product, with no corresponding effect on the price of the branded product.

152. The data available since the entry of Endo's authorized generic version of Lidoderm confirm the unique competitive impact of such entry on generic Lidoderm sales and prices. By September 2014, Endo's authorized generic product had captured over 40% of generic lidocaine patch unit sales, and authorized generic competition had lowered the average price of generic lidocaine patches by more than 16%. Endo's efforts to discount the branded product had no comparable effect on generic prices.

153. If Watson were already facing robust competition to its generic lidocaine patch, then the entry of Endo's authorized generic version of Lidoderm would not erode the sales volume of Watson's generic lidocaine patch or the price of lidocaine patches so rapidly and dramatically.

154. In addition, although a branded product is therapeutically equivalent to its generic counterpart, a unique competitive dynamic exists between generics. Typically, retail pharmacies stock the brand product plus one generic version. Thus, while the brand company can expect its product to be available at every pharmacy, generic companies must compete against one another to be a pharmacy's primary generic supplier. Price is the primary mechanism of such competition. Consequently, entry of additional generic competitors drives down the average

generic price, often to a fraction of the brand's pre-generic-entry price.

155. The initial price offered by the first generic entrant is typically a percentage off the brand's list price (or WAC). But after the initial generic sales, any correlation between the prices of the branded product and the generic products generally dissipates. Branded prices often rise after generic entry as brand companies extract additional profits from those patients who are not price sensitive and continue to buy the branded product, while generic prices fall as more generic products come to market. The head of Endo's Pain Management business summarized this dynamic as follows: "Nobody considers an average price of brand plus generic because they operate in a different dynamic." Instead, "generic pricing tend[s] to be a function of how many competitive players are there in the generic market."

156. Potential sellers of generic lidocaine patches face substantial barriers to entry, including obtaining FDA approval, costly specialized equipment and facilities to manufacture the product, and Endo's ability to trigger an automatic 30-month stay of FDA approval by filing a patent infringement lawsuit.

157. Before May 2014, Watson held a 100% share of the relevant market for generic lidocaine patches.

## VIII. Harm to Consumers and Competition

### A. The Opana ER Agreement eliminated the risk of generic competition for 2½ years

158. By impeding generic competition, Endo's and Impax's conduct denied consumers and other purchasers of Opana ER access to AB-rated generic versions of Opana ER that would offer the same therapeutic benefit as branded Opana ER but at a fraction of the price.

159. The agreement between Endo and Impax precluding Impax from launching a generic version of Opana ER until January 2013 harmed competition and consumer welfare by

eliminating the risk that Impax would have marketed its generic version of Opana ER before that date. Through their agreement, Endo eliminated the potential that: (1) Impax would have launched its generic version of Opana ER before January 2013; or (2) Endo would have agreed to settle the patent litigation on terms that did not compensate Impax, but provided for generic entry earlier than January 2013.

160. Before the Opana ER Agreement, Impax had been preparing to enter with a generic version of Opana ER as early as FDA approval, which it received in June 2010. That entry would have quickly and significantly reduced Endo's market share, promoted economic efficiency, and led to significant price reductions for extended-release oxymorphone products. Impax abandoned its generic entry plans because it received a share of Endo's monopoly profits in the form of the Guaranteed No-AG Payment and the Side Deal Payment. Without the large payment, Impax would have launched its generic version of Opana ER prior to January 2013.

161. Entry of Impax's generic product would have given consumers the choice between branded Opana ER and lower-priced AB-rated substitutes for Opana ER. Many consumers would have purchased lower-priced AB-rated generic drugs rather than higher-priced branded Opana ER. Endo's contemporaneous forecasts assumed that approximately 85% of Opana ER unit sales would switch to an AB-rated generic version of Opana ER. Consumers likely would save hundreds of millions of dollars by purchasing generic versions of Opana ER. By entering into their anticompetitive agreement, Endo and Impax shared additional monopoly profits at the expense of consumers.

162. Endo's agreement with Impax also prevented competition from other potential generic oxymorphone ER manufacturers for the most prescribed strengths of generic Opana ER, comprising 95% of total Opana ER sales. Under the Hatch-Waxman Act, Impax had 180-day exclusivity for those strengths, which prohibited the FDA from approving any other generic

versions of Opana ER for those strengths until Impax's 180-day exclusivity period either expired or was forfeited. Because of Endo's anticompetitive agreement with Impax, the 180-day exclusivity period did not begin to run until January 2013, the entry date Endo paid Impax to accept. The Opana ER Agreement, therefore, precluded all generic Opana ER competition for the most prescribed strengths until January 2013. As a result of this conduct, Endo maintained its oxymorphone ER monopoly for 2½ years, allowing it to charge supracompetitive prices for Opana ER.

163. In addition, the Opana ER Agreement harmed consumers by facilitating Endo's strategy to switch patients from Original Opana ER to Reformulated Opana ER before a generic version of Original Opana ER entered. Absent this agreement, Impax likely would have entered the market with an AB-rated generic version of Original Opana ER before Endo's introduction of its reformulated version, which did not receive FDA approval until December 2011. According to Endo's own forecasts, an AB-rated generic version of Opana ER would have quickly captured a significant share—85% or more—of the extended-release oxymorphone market. And Endo expected that only 30% to 32% of the market would switch to Reformulated Opana ER if Impax's generic version of Original Opana ER was available at the time Endo introduced Reformulated Opana ER.

164. Having successfully forestalled generic competition, however, Endo succeeded in switching the market to the reformulated version and withdrawing Original Opana ER from the market before Impax could enter in 2013. When Impax finally did enter, its generic product was not AB rated to the only marketed Opana ER formulation, preventing pharmacies from automatically substituting it for the brand. Consequently, Impax's generic captured a smaller share—15% to 30%— of oxymorphone ER unit sales in the first 18 months than it would have as an AB-rated product. By giving Endo the time it needed to switch the market to Reformulated

Opana ER, the Opana ER Agreement continues to foreclose AB-rated generic competition to the detriment of consumers.

### B. The Lidoderm Agreement eliminated the risk of generic competition for more than one year

165. By impeding generic competition, Endo, Teikoku, and Watson's conduct denied consumers and other purchasers of Lidoderm access to AB-rated generic versions of Lidoderm that would offer the same therapeutic benefit as branded Lidoderm, but at a lower price.

166. The agreement between Endo, Teikoku, and Watson precluding Watson from launching a generic version of Lidoderm until September 2013 harmed competition and consumer welfare by eliminating the risk that Watson would have marketed its generic version of Lidoderm before September 2013. Through their agreement, Endo and Teikoku eliminated the potential that: (1) Watson would have launched its generic Lidoderm before September 2013; or (2) Endo and Teikoku would have agreed to settle the patent litigation on terms that did not compensate Watson, but provided for generic entry earlier than September 2013.

167. Before the Lidoderm Agreement, Watson was preparing to launch its generic lidocaine patch as early as FDA approval, which it received in August 2012. Watson did not plan to wait until an appeals court decision in patent litigation before launching its generic product. Watson's generic entry would have quickly and significantly reduced Endo's market share, promoted economic efficiency, and led to significant price reductions for lidocaine patches. Indeed, when Watson ultimately launched its generic version of Lidoderm in September 2013, Endo immediately responded by providing bigger discounts to retain Lidoderm's preferred position on certain drug formularies.

168. Watson abandoned its generic entry plans because it received a share of Endo and Teikoku's monopoly profits in the form of the No-AG Payment and the Free Product Payment.

Without the large payment, Watson would have launched its generic version of Lidoderm prior to September 2013.

169. Entry of Watson's generic product would have given consumers the choice between branded Lidoderm and lower-priced generic substitutes for Lidoderm. Many consumers would have chosen to purchase the lower-priced generic version instead of higher-priced branded Lidoderm. In its contemporaneous forecasts, Endo predicted its Lidoderm revenues would decrease by at least $500 million during the first year after generic entry. As a result of this generic competition, consumers would have saved hundreds of millions of dollars. By entering into their anticompetitive agreement, Endo, Teikoku, and Watson have shared additional monopoly profits at the expense of consumers.

### C. The Lidoderm No-AG Payment reduced competition for generic lidocaine patches for 7½ months

170. The Lidoderm Agreement further harmed competition and consumers by eliminating competition for sales of generic lidocaine patches until May 2014.

171. Before the Lidoderm Agreement, Endo and Watson were potential competitors in the sale of generic lidocaine patches. Indeed, Endo's authorized generic was the only potential generic competition to Watson's generic lidocaine patch during Watson's 180-day exclusivity period for generic Lidoderm. Under the Hatch-Waxman Act, the FDA was prohibited by law from approving any other generic version of Lidoderm until Watson's 180-day exclusivity period had expired or been forfeited. Endo, however, was legally entitled to market an authorized generic version of its own Lidoderm product at any time, including during the first filer's exclusivity period.

172. Before the Lidoderm Agreement, Endo was planning to launch an authorized generic as soon as Watson launched its generic lidocaine patch. Under its agreement with

Teikoku, Endo had the exclusive right to sell an authorized generic version of Lidoderm in the United States. Endo also had the financial incentive to do so. As soon as Watson entered with its generic product, Endo could sell an authorized generic to compete for sales to generic lidocaine users, while preserving branded Lidoderm sales for the minority of users who were willing to pay more for the branded product. Endo estimated that it could make more than $150 million in net sales during the first year after generic entry by selling an authorized generic in competition with Watson.

173. Under the Lidoderm Agreement, however, Watson acquired an exclusive field-of-use license that prevented Endo from launching an authorized generic until May 2014. By eliminating the potential competition between Endo's authorized generic and Watson's generic version of Lidoderm, this acquisition substantially reduced competition in the market for generic lidocaine patches.

174. As a result of Endo and Watson's conduct, competition between generic lidocaine patches was delayed for 7½ months until May 2014. Absent Endo's commitment not to compete with an authorized generic, Endo would have launched an authorized generic at or near the time of Watson's generic lidocaine patch entry. Endo's authorized generic entry would have resulted in significantly lower prices for generic lidocaine patches and hundreds of millions of dollars in savings for generic lidocaine patch purchasers. Instead, Endo and Watson shared additional profits at the expense of consumers.

175. Upon termination of the exclusive field-of-use license, Endo immediately launched a Lidoderm authorized generic through its subsidiary, Qualitest. Competition from Endo's authorized generic product caused the price of generic lidocaine patches to quickly fall by 16% or more. This significant price reduction is consistent with Endo's and Watson's

contemporaneous forecasts as well as the empirical literature on the price effects of authorized generic competition.

176. The partially exclusive nature of Watson's license resulted in no cognizable benefits to counteract the harm caused by the absence of competition from an authorized generic.

177. Endo's commitment not to compete with an authorized generic was not reasonably related to achieving any cognizable benefits of a larger procompetitive venture.

178. Because of barriers such as FDA approval, entry by other firms would not deter or counteract the competitive effects of eliminating an authorized generic.

**Count I**

**Restraint of Trade – Against Endo and Impax (Opana ER)**

179. Plaintiffs re-allege and incorporate by reference the allegations in all of the paragraphs above.

180. The agreement between Endo and Impax that Impax would not compete by marketing oxymorphone ER until January 2013 constitutes an unfair method of competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

**Count II**

**Monopolization – Against Endo (Opana ER)**

181. Plaintiffs re-allege and incorporate by reference the allegations in all of the paragraphs above.

182. Endo's willful maintenance of its monopoly in the oxymorphone ER market through a course of anticompetitive conduct, including its entry into an unlawful agreement with Impax, constitutes an unfair method of competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

**Count III**

**Restraint of Trade – Against Endo, Teikoku, and Watson (Lidoderm)**

183. Plaintiffs re-allege and incorporate by reference the allegations in all of the paragraphs above.

184. The agreement among Endo, Teikoku, and Watson that Watson would not compete by marketing lidocaine patch until September 2013 constitutes an unfair method of competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

**Count IV**

**Monopolization – Against Endo (Lidoderm)**

185. Plaintiffs re-allege and incorporate by reference the allegations in all of the paragraphs above.

186. Endo's willful maintenance of its monopoly in the lidocaine patch market through a course of anticompetitive conduct, including its entry into an unlawful agreement with Teikoku and Watson, constitutes an unfair method of competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

**Count V**

**Restraint of Trade – Against Endo and Watson**
**(generic lidocaine agreement not to compete)**

187. Plaintiffs re-allege and incorporate by reference the allegations in all of the paragraphs above.

188. The agreement between Endo and Watson that Endo would not compete in the market for generic lidocaine patches until May 2014 constitutes an unfair method of competition in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

**Count VI**

**Unlawful Acquisition – Against Watson and Endo**
**(generic lidocaine patch exclusive license)**

189. Plaintiffs re-allege and incorporate by reference the allegations in all of the paragraphs above.

190. Watson's acquisition of an exclusive field-of-use license from Endo substantially lessened competition in the generic lidocaine patch market in violation of Section 7 of the Clayton Act, 15 U.S.C. § 18.

**Prayer for Relief**

WHEREFORE, Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), empowers this Court to issue a permanent injunction against violations of the FTC Act and, in the exercise of its equitable jurisdiction, to order ancillary equitable relief to remedy the injury caused by Defendants' violations; therefore, the FTC requests that this Court, as authorized by 15 U.S.C. § 53(b), 15 U.S.C. § 26, and its own equitable powers, enter final judgment against Defendants on Counts I, II, III, IV, V, and VI declaring, ordering, and adjudging:

1. That the agreement between Endo and Impax violates Section 5(a) of the FTC Act, 15 U.S.C. § 45(a);
2. That Endo's course of conduct, including its entry into an unlawful agreement with Impax, violates Section 5(a) of the FTC Act, 15 U.S.C. § 45(a);
3. That the agreement among Endo, Teikoku, and Watson violates Section 5(a) of the FTC Act, 15 U.S.C. § 45(a);
4. That Endo's course of conduct, including its entry into an unlawful agreement with Teikoku and Watson, violates Section 5(a) of the FTC Act, 15 U.S.C. § 45(a);
5. That Watson's acquisition of an exclusive field-of-use license from Endo violates

Section 7 of the Clayton Act, 15 U.S.C. § 18;

6. That defendants are permanently enjoined from engaging in similar and related conduct in the future, including, but not limited to entering into:

    a. Agreements that, in form or substance, involve payment from the brand company to the generic company and the generic company's agreement to refrain from competing for some period of time; and

    b. Agreements that, in form or substance, prevent, restrict, or disincentive the brand manufacturer from competing with an authorized generic version of its product for some period of time; and

7. That the Court grant such other equitable relief as the Court finds necessary, including restitution or disgorgement, to redress and prevent recurrence of defendants' violations of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), as alleged herein.

Dated: March 30, 2016

Respectfully Submitted,

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